

## REMARKS

Applicants have studied the Office Action dated July 31, 2001, and have made amendments to the claims. By virtue of this amendment, claims 13-19, 22-37, and 42-69 are pending. Claims 1-12, 20-21, 38-41 have been canceled without prejudice or disclaimer, claims 13-15, 23, 24, 26, 33-35, and 42 have been amended, and new claims 43-69 have been added. It is submitted that the application, as amended, is in condition for allowance. Reconsideration and allowance of all of the claims in view of the above amendments and the following remarks are respectfully requested.

Claims 1-3, 12-13, 15-16, 21, 23-26, and 34-42 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,068,536 to Rosenthal. This rejection is respectfully traversed.

To better organize the claims and to clearly distinguish over the Rosenthal reference, rejected claims 1-3, 12, 21, and 38-41 have been canceled, without prejudice or disclaimer. Accordingly, as applied to claims 1-3, 12, 21, and 38-41, the rejection is now moot.

The applicants have also amended claims 13, 15-16, 23-26, and 42 to distinguish over the Rosenthal reference.

Embodiments of the present invention are directed to sampling glucose monitor data and calibrating the results with an independent reference point to properly interpret the sampled values. Particular embodiments are directed to first collecting data over a period of time and then calibrating the collected data retrospectively by the described post process. Independent claim 13 recites "sampling glucose monitor data at a predetermined rate from a glucose sensor over a period of time... and interpreting the sampled glucose monitor data collected during the period of time retrospectively using the calibration factor post process" (emphasis added). Similarly, apparatus claim 42 recites "means for sampling glucose monitor data ... and means for interpreting the sampled glucose monitor data collected during the period of time retrospectively using the calibration equation post process" (emphasis added). The Rosenthal

reference does not disclose, teach or suggest respectively using calibration data to post process sampled glucose monitor data.

As stated in the Rosenthal reference at col. 4, lines 8-9, “the method of the present invention is utilized to calibrate a near-infrared analysis instrument.” This near-infrared analysis instrument does not sample readings from a glucose monitor, but instead takes discrete optical measurements at distinct points in time, and is essentially a non-invasive glucose meter that must be calibrated against the very devices it seeks to replace. The Rosenthal reference does describe that “optical measurements should be made approximately once per minute. A total of approximately 60 sets of optical information will be recorded in the preferred embodiment.” But these sixty separate measurements are performed for initializing the near-infrared analysis instrument during the calibration phase (see col. 4, lines 4-7). As seen from the description of calibration process in the Rosenthal reference, “a set of four actual finger poke measurements will provide information for approximately sixty sets of the near-infrared optical measurements” (see col. 4, line 31-34). Thus, the calibration process is specifically designed to initialize the instrument for future optical measurements (as a replacement for a finger stick meter), not to interpret the data collected for data processing procedures. Accordingly, it is respectfully submitted that amended claims 13 (and thus dependent claims 15-16, 23-26) and 42 are patentable over the Rosenthal reference.

Other embodiments of the present invention are directed to a process for sampling glucose monitor data and pre-processing the data before calibration is applied. In particular, claim 34 recites “deriving interval values by applying clipping limits and averaging the post-clipped sampled glucose monitor data over a predetermined interval rate [and] deriving at least one glucose monitor data point by averaging the derived interval values at a predetermined memory storage rate” (emphasis added). Independent claim 35 recites similar language. In addition, newly added independent claim 60 also recites “deriving interval values by applying clipping limits and averaging the post-clipped sampled glucose monitor data over a predetermined interval rate; [and] deriving at least one glucose monitor data point by averaging the derived interval values at a predetermined memory storage rate” (emphasis added). Newly

added dependent claims 44-59 depend from independent claim 34 and newly added dependent claims 61-69 depend from new independent claim 60, and thus recite similar language.

It is respectfully submitted that the Rosenthal reference does not describe, teach or suggest the limitations in amended claims 34-37 or in new claims 44-69. Nowhere in the cited sections of the Rosenthal reference does it describe a pre-processing of the optical measurements before the calibration adjustments are made. Instead, the Rosenthal reference only teaches a method of deriving a calibration factor, not a method of pre-processing the optical measurements before the calibration factor is applied. Accordingly, it is respectfully submitted that amended claims 34 (and dependent claims 44-59) and 35 (and dependent claims 36-37), and new claim 60 (and dependant claims 61-69) are patentable over the Rosenthal reference.

Therefore, it is respectfully submitted that the rejection of claims 1-3, 12-13, 15-16, 21, 23-26, and 34-42 under 35 U.S.C. § 102(b) should be withdrawn.

Claims 1-2, 6-8, 11-15, 19-25, 34-36, and 38-42 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,507,288 to Bocker et al. This rejection is respectfully traversed.

To better organize the claims and to clearly distinguish over the Bocker et al. reference, rejected claims 1-2, 6-8, 11-12, 20-21, 38-41 have been canceled without prejudice or disclaimer. Accordingly, as applied to claims 1-2, 6-8, 11-12, 20-21, and 38-41, the rejection is now moot.

Embodiments are directed to computing an appropriate calibration factor by deriving at least one glucose monitor data point and comparing it with at least one reference source, and then interpreting the collected data retrospectively by using the calibration factor post process. For example, independent claim 13 recites “sampling glucose monitor data at a predetermined rate from a glucose sensor over a period of time, deriving at least one glucose monitor data point from the sampled glucose monitor data at a predetermined memory storage rate; ... calculating a calibration factor using the at least one blood glucose reference reading and the corresponding at least one glucose monitor data point; and interpreting the sampled glucose monitor data collected

during the period of time retrospectively using the calibration factor post process” (emphasis added). Independent claim 42 recites similar language. The Bocker et al. reference does not disclose, teach or suggest deriving at least one data point, using the at least one data point to calculate a calibration factor, and then retrospectively interpreting the data using the calibration factor post process, as recited in the claims.

The Bocker et al. reference teaches “a non-invasive sensor-analysis-system” where “the preferred embodiment includes light irradiating means which may be LEDs mounted in the sensor 7 itself” (see col. 4, lines 3-4 and col. 6, line 34-35). “By means of its sensor operation device 32 and evaluation electronics 33, the sensor 7 generates sensor-analysis data  $C_S$ ” (See col. 7, lines 42- 44). “A  $C_A$  value becomes available when the patient stabs his/her finger to obtain a drop of blood” (See col. 7, lines 34-36). The Bocker et al. reference (in col. 7, lines 49-54), teaches: “element-analysis data  $C_A$  are used to calibrate the sensor-analysis data  $C_S$ . This procedure may be carried out for instance in such a way that at each calibration time  $t_1$  through  $t_5$  the sensor calibration means 30 compares the analytical data  $C_A$  and  $C_S$  stored in the memory 26.” In other words, the calibration in the Bocker et al. reference calibrates by simply making the  $C_A$  and  $C_S$  equal (as best seen in Fig. 3 of the Bocker et al. reference) and modifying the evaluation curve  $C_S=g(S)$  to fit the calibrated  $C_S$  at certain periods of time. Thus, any erroneous or unusual data points are used in the calibration. The Bocker et al. reference does not disclose, teach, or suggest deriving at least one data point from the sampled glucose data and using the at least one data point to calculate a calibration factor which will be applied in a post process procedure. Conversely, as recited in the claims, by using a derived data point rather than simply correcting a sampled reading, a better overall calibration estimate is achieved even if it means that the calibrated monitor data will not always be equal to the reference reading at specific times that the reference readings are taken. Accordingly, it is respectfully submitted that amended claims 13-15, 19, 22-25, and 42 are patentable over the Bocker et al. reference.

Claims 14 and 15 are further distinguished from the Bocker et. al reference. Claim 14 recites “the step of calculating a calibration factor further includes taking account of at least one previous calibration factor to calculate a new calibration factor” (emphasis added). Claim 15

recites “the step of calculating the calibration factor uses the at least two blood glucose reference readings and the corresponding at least one glucose monitor data point” (emphasis added).

It is respectfully submitted that the Bocker et al. reference does not suggest the limitations in claims 14 and 15. The Bocker et al. reference states “a backward correction to the time  $t_1$  may be achieved on the basis of the concentration value  $C_A(t_2)$  obtained at time  $t_2$ . Similar considerations apply to going back from the time  $t_3$  to the time  $t_2$ , etc.” (See col. 7, line 65 – col. 8, line 1). Nowhere in the cited sections of the Bocker et al. reference does it disclose, teach or suggest taking account of at least one previous calibration factor to calculate a new calibration factor. Moreover, the Bocker et al. reference does not disclose, teach or suggest a calibration technique where at least two blood glucose reference readings corresponds with at least one glucose monitor data point. Accordingly, it is respectfully submitted that amended claims 14 and 15 are further patentable over the Bocker et al. reference.

Other embodiments of the present invention are directed to a process for sampling glucose monitor data and pre-processing the data before calibration is applied. For example, the embodiments claimed in independent claim 34 recite: “deriving interval values by applying clipping limits and averaging the post-clipped sampled glucose monitor data over a predetermined interval rate [and] deriving at least one glucose monitor data point by averaging the derived interval values at a predetermined memory storage rate (emphasis added).” Amended independent claim 35 recites similar language. In addition, newly added independent claim 60 also recites: deriving interval values by applying clipping limits and averaging the post-clipped sampled glucose monitor data over a predetermined interval rate; [and] deriving at least one glucose monitor data point by averaging the derived interval values at a predetermined memory storage rate (emphasis added).” Newly added dependent claims 44-59 depend from independent claim 34 and newly added dependent claims 61-69 depend from independent claim 60, and thus recite similar language.

It is respectfully submitted that the Bocker et al. reference does not describe, teach, or suggest the limitations in amended claims 34-36 or in new claims 44-69. Nowhere in the cited sections of the Bocker et al. reference does it describe a pre-processing of the sensor analysis

data before the calibration adjustments are made. Instead, the Bocker et al. reference only teaches a method of comparing element-analysis data  $C_A$  to the sensor analysis data  $C_S$ , where from “said comparison a new corrected evaluation curve  $C_S=g(S)$ ” is derived (See col. 7, lines 49-60). The Bocker et al. reference does not teach a method of pre-processing the sensor analysis data before the calibration factor is applied. Accordingly, it is respectfully submitted that amended claims 34 (and thus dependant claims 44-59) and 35 (and thus dependent claim 36) and new claim 60 (and dependent claims 61-69) are patentable over the Bocker et al. reference.

Therefore, it is respectfully submitted that the rejection of claims 1-2, 6-8, 11-15, 19-25, 34-36, and 38-42 under 35 U.S.C. § 102(b) should be withdrawn.

Claim 13 was further rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,497,772 to Schulman et al. This rejection is respectfully traversed.

Claim 13 recites “sampling glucose monitor data at a predetermined rate from a glucose sensor over a period of time, deriving at least one glucose monitor data point from the sampled glucose monitor data at a predetermined memory storage rate; ... calculating a calibration factor using the at least one blood glucose reference reading and the corresponding at least one glucose monitor data point; and interpreting the sampled glucose monitor data collected during the period of time retrospectively using the calibration factor post process” (emphasis added). The cited sections of the Schulman et al. reference do not teach any specific calibration techniques as recited in claim 13. In particular, the Schulman et al. reference does not disclose deriving a glucose monitor data point, calculating a calibration factor using the glucose monitor data point, nor interpreting the sampled glucose monitor data retrospectively using the calibration factor post process. Instead, the Schulman et al. reference teaches calibrating the glucose monitor system “with each new glucose sensor. Further, periodically, e.g., once every 24 hours, the system is calibrated against a blood sample that has been independently analyzed by a certified reference method for glucose concentration” (col. 3, line 37-41). In other words, the Schulman et al. reference teaches performing calibration to initialize the instrument for future glucose measurements and periodically checking to make sure the instrument is still calibrated, and does

not describe using this calibration to interpret the data previously collected. Therefore, it is respectfully submitted that the rejection of claim 13 under 35 U.S.C. § 102(b) be withdrawn.

Claims 4 and 17 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent 5,068,536 to Rosenthal as applied to claims 3 and 16 in view of U.S. Patent 5,813,403 to Soller et al. This rejection is respectfully traversed.

Claim 4 has been canceled without prejudice or disclaimer, and the rejection as applied to claim 4 is now moot.

Claim 17 depends from claim 16, which is patentably distinguished over the Rosenthal reference as discussed above. Accordingly, claim 17 is also distinguished over the Rosenthal reference.

The Soller et al. reference does not make up for the deficiencies of the Rosenthal reference. The Soller et al. reference is directed to “an optical method for determining the pH of a tissue disposed underneath a covering tissue, e.g. skin, of a patient” (col. 2, lines 7-9). The Examiner cited the Soller et al. reference for the proposition that “it is well known in the art that linear regression algorithms such as least squares fitting is used for x-y arrays of data points.” The combination of the Soller et al. reference with the Rosenthal reference does not describe, teach, suggest or otherwise render obvious the claimed subject matter because the cited sections of the Soller et al. reference do not disclose, teach or suggest a method for “sampling glucose monitor data at a predetermined rate from a glucose sensor over a period of time... and interpreting the sampled glucose monitor data collected during the period of time retrospectively using the calibration factor post process” (emphasis added)” as recited in claim 17. Therefore, it is respectfully submitted that the rejection of claims 4 and 17 under 35 U.S.C. § 103(a) should be withdrawn.

Claims 5 and 18 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent 5,068,536 to Rosenthal as applied to claims 1 and 13 and in view of U.S. Patent 5,830,133 to Osten et al. This rejection is respectfully traversed.

Claim 5 has been canceled without prejudice or disclaimer, and the rejection as applied to claim 5 is now moot.

Claim 18 depends on claim 13, which is patentably distinguished over the Rosenthal reference as discussed above. Accordingly, claim 18 is also distinguished over the Rosenthal reference.

The Osten et al. reference does not make up for the deficiencies of the Rosenthal reference. The Osten et al. reference is directed to “a method for rapidly, inexpensively, and accurately characterizing the properties of matter of biological origin containing water by analyzing the near-infrared spectrum of the biological matter” (col. 3, lines 41-44). The Examiner cited the Osten et al. reference for the proposition that “it is well known in the art that regression algorithms such as linear regression, stepwise regression, and partial least squares regression are used to develop a statistical correlation between measurements and variables being quantified.” The combination of the Osten et al. reference with the Rosenthal reference does not describe, teach, suggest or otherwise render obvious the claimed subject matter because the cited sections of the Osten et al. reference do not disclose, teach or suggest a method for “sampling glucose monitor data at a predetermined rate from a glucose sensor over a period of time... and interpreting the sampled glucose monitor data collected during the period of time retrospectively using the calibration factor post process” (emphasis added), as recited in claim 18. Therefore, it is respectfully submitted that the rejection of claims 5 and 18 under 35 U.S.C. § 103(a) should be withdrawn.

Claims 9-10 and 32-33 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent 5,068,536 to Rosenthal as applied to claims 1 and 13 in view of U.S. Patent 6,049,727 to Crothall et al. and U.S. Patent 5,885,211 to Eppstein et al. This rejection is respectfully traversed.

Claims 9-10 have been canceled without prejudice or disclaimer, and the rejection as applied to claims 9-10 is now moot.

Claims 32-33 depend on claim 13, which is patentably distinguished over the Rosenthal reference as discussed above. Accordingly, claims 32-33 are also distinguished over the Rosenthal reference.

The Crothall et al. reference and/or the Eppstein et al. reference do not make up for the deficiencies of the Rosenthal reference. The Crothall et al. reference is directed to “methods and apparatus for determining concentration of constituents of body fluids in a mammal using in vivo spectroscopy” (col. 6, lines 13-15). The Examiner cited the Crothall et al. reference because “Crothall teaches a system that monitors blood glucose levels in interstitial fluid... and it would have been obvious ... to substitute the optical sensor of Rosenthal for the interstitial fluid sensor of Crothall” (See page 6, line 18 – page 7, line 9 of the Office Action). On the other hand, the Eppstein et al. reference is directed to “a rapid and painless method of eliminating the barrier function of the stratum corneum to facilitate the transcutaneous transport of therapeutic substances into the body when applied topically or to access the analytes within the body for analysis” (col. 12, lines 48-52). The Examiner cited the Eppstein et al. reference for the proposition that “Eppstein et al. teaches ... that data sets of individuals are analyzed to determine the time shift required to achieve the maximum correlation between the interstitial glucose levels and the blood glucose levels.” The combination of the Crothall et al. and/or the Eppstein et al. references with the Rosenthal reference does not describe, teach, suggest or otherwise render obvious the claimed subject matter because the cited sections of the Crothall et al. and Eppstein et al. references do not disclose, teach or suggest a method for “sampling glucose monitor data at a predetermined rate from a glucose sensor over a period of time... and interpreting the sampled glucose monitor data collected during the period of time retrospectively using the calibration factor post process” (emphasis added), as recited in claims 32-33. Therefore, it is respectfully submitted that the rejection of claims 9-10 and 32-33 under 35 U.S.C. § 103(a) should be withdrawn.

Claims 26-31 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent 5,497,772,536 to Schulman et al. as applied to claim 13 in view of U.S. Patent 4,786,394 to Enzer et al. This rejection is respectfully traversed.

Claims 26-31 depend on claim 13, which is patentably distinguished over the Schulman et al. reference as discussed above. Accordingly, claims 26-31 are also distinguished over the Schulman et al. reference.

The Enzer et al. reference does not make up for the deficiencies of the Rosenthal reference. The Enzer et al. reference is directed to blood gas analysis system, which uses electrodes to generate electrical signals to measure distinct characteristics of the blood sample. (see col. 3, lines 56 – col. 4, line 5). The combination of the Enzer et al. reference with the Schulman reference does not describe, suggest or otherwise render obvious the claimed subject matter because the cited sections of the Enzer et al. reference do not disclose, teach or suggest a method for “sampling glucose monitor data at a predetermined rate from a glucose sensor over a period of time, deriving at least one glucose monitor data point from the sampled glucose monitor data at a predetermined memory storage rate; ... calculating a calibration factor using the at least one blood glucose reference reading and the corresponding at least one glucose monitor data point; and interpreting the sampled glucose monitor data collected during the period of time retrospectively using the calibration factor post process” (emphasis added), as recited in claims 26-31.

Claim 26 (and claims 27-31, which depend from claim 26) is further distinguished by reciting “wherein one or more calculations for calculating a first calibration factor is different than one or more calculations for calculating all subsequent calibration factors” (emphasis added). In addition, newly added claim 53 (and claims 54-59) also recites similar language.

It is respectfully submitted that the Schulman et al. and Enzer et al. references do not suggest the limitation in claim 26 (and thus claims 27-31) or in new claims 53-59. As the Examiner stated on page 6, line 21- page 7, line 1 of the Office Action, the “Schulman et al. does not teach that subsequent calibration factors are calculated differently from the first calibration factor.” In addition, the Enzer et al. reference states: “for most subsequent interval assays, a one-point recalibration of the electrodes 62-69 is made; occasionally, a two-point recalibration is initiated by the microprocessor 100 to ensure continued accuracy” (emphasis added) (See col.

11, lines 54-57). However, occasionally applying a different calibration is not the same as calculating a calibration factor using a different calculation for all subsequent calibration factors.

In addition, claim 28 is further distinguished by reciting, "the single-point calibration includes an offset value." In addition, newly added claim 56 recites similar language.

Although the Examiner stated in page 8, line 10-12 of the Office Action that "in regard to claim 28, Schulman et al. teaches in column 15, line 18 to column 18, line 27 that the single-point calibration includes an offset called INTERCEPT," the applicants were unable to find any reference to an offset called intercept in the cited sections. In addition, when the applicants conducted a word search for "intercept" in the Schulman et al. reference and the Enzer et al. reference, no match for "intercept" was found. Established law states that if the Examiner asserts an explicit or implicit teaching or suggestion in the prior art, then the Examiner must indicate where such teaching or suggestion appears in the prior art itself. In re Rijckaert 9 F.3d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993); In re Yates, 663 F.2d 1054, 211 USPQ 1149, 1151 (CCPA 1981). In the present case, there is no teaching or suggestion of the claimed invention in either the Schulman et al. or Enzer et al. references that the first calibration factor uses a single-point calibration equation with an offset value. The cited references therefore fail to provide the basis for a prima facie case of obviousness.

Therefore, it is respectfully submitted that the rejection of claims 26-31 under 35 U.S.C. § 103(a) should be withdrawn.

New claims 43-69 have been added by this amendment and are provided to further define the present invention. For example new claims 60-69 describe an article of manufacture containing code performing the steps described in independent claim 34. In addition, claims 44 and 45, which depend from claim 34, and claims 61 and 62, which depend from claim 60, further distinguish the present invention over the cited references by adding additional steps performed in pre-processing the sampled data before calibration is applied. Additional comments were also made throughout the Amendment to distinguish the new claims from the cited references.

Therefore, in light of the above remarks, it is respectfully submitted that claims 13-19, 22-37, and 42-69 are in condition for allowance.

No amendment made was related to the statutory requirements of patentability unless expressly stated herein; and no amendment made was for the purpose of narrowing the scope of any claim, unless Applicant has argued herein that such amendment was made to distinguish over a particular reference or combination of references.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Northridge, California, telephone number (818) 576-4110, to discuss the steps necessary for placing the application in condition for allowance.

Respectfully submitted,

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